

*FDA Improvement Act of 2010 Creates Independence between FDA & Drug Industry, Establishes New Post-Marketing Safety Center, Requires More Truthful Drug Company Advertising, & Eliminates FDA Advisory Panels' Conflicts Of-Interest*

Washington, DC - Congressman Maurice Hinchey (D-NY) today introduced the Food and Drug Administration (FDA) Improvement Act of 2010, a sweeping reform bill that would end the financial link and inappropriately close relationship between the pharmaceutical industry and the FDA, vastly improve the agency's post-market drug safety operations, impose fees on drug company advertising to better monitor such ads, and eliminate conflicts-of-interest on FDA advisory committees.

"While the Food and Drug Administration has made some important positive changes under the Obama administration, the agency as an institution remains too closely tied to the pharmaceutical industry. The FDA continues to operate without the sufficient independent authority needed to protect the people it was created to serve. It's a situation that has allowed the interests of powerful pharmaceutical companies to come before those of the American people and that's simply a situation that needs to come to an end," Hinchey said. "The Food and Drug Administration Improvement Act will dramatically reshape the FDA, improve its drug safety efforts, and fully guarantee that the public health is the agency's singular concern."

To create independence at the FDA, Hinchey's bill would prohibit the agency from collecting fees paid by companies it regulates. Instead, those funds would be deposited into the general fund of the Treasury. In an effort to ensure there is no reduction in FDA services as a result of the loss of those fees, Hinchey's measure provides mandatory funding levels that would be appropriated by Congress to ensure no services are lost. By doing so, the FDA would be fully funded by and accountable to the U.S. taxpayers, instead of drug manufacturers. Currently, the FDA is dependent upon drug company money and is required to negotiate with those companies how that money can be spent. Hinchey said that this back-and-forth between the FDA and the drug companies significantly compromises the FDA's ability to protect the American people from dangerous products.

Hinchey's FDA Improvement Act also establishes an independent Center for Post-Market Drug, Device and Biologic Safety & Effectiveness, which would monitor all approved drugs and create standards for drug advertisements. Currently, the same people who approve a drug are also responsible for regulating the product after it hits the market. Such a scenario may make it difficult to take a drug off the market because the officials who approve a medication may not

want to admit a mistake by later deeming it unsafe. The Center for Post-Market Drug Safety & Effectiveness would be located within the FDA and staffed by professional scientific analysts who will be independent of the initial approval process. The Secretary of Health and Human Services would appoint the Center's director. The Center would also be given increased funding and authorities to improve the FDA's post-market monitoring process.

The congressman's bill would also empower the FDA with the authority to mandate that companies conduct post-marketing studies of FDA-approved drugs. Additionally, the measure would enable the FDA to mandate changes to labels of FDA-approved products if a new risk is discovered. The bill would also require the Secretary of Health and Human Services to review and revise the FDA's regulations pertaining to drug labeling to improve the clarity of drug labeling and make labels easier to read.

"The FDA Improvement Act offers common sense solutions to vastly improve the FDA's ability to protect the public and ends the close relationship that currently exists between the FDA and the pharmaceutical industry," Hinchey said. "For far too long the FDA has been structured in a way that benefits the drug companies and undermines the agency's ability to properly regulate these products."

In an effort to better ensure truth in advertising by drug and device manufacturers, Hinchey's FDAIA imposes new fees on drug and device advertisements in order to raise funding for the FDA to help oversee and regulate these kinds of advertisements. The bill also would require all direct-to-consumer advertisements to include a toll-free phone number to allow consumers to report negative side effects of prescription drugs to the FDA.

Hinchey's bill also addresses conflicts-of-interest that arise among members of the FDA's advisory committees. The FDA relies on outside advisory panels to provide recommendations on the safety and effectiveness of drugs and medical devices. However, in some instances, scientists who have served on these panels have financial conflicts-of-interest that bias their recommendations, or at least give the perception of bias. The FDAIA would require that all FDA advisory panels be composed of qualified experts who do not have any financial ties to companies who have a stake in the topic under discussion.

Additionally, the FDA Improvement Act would ensure the public could hold medical device manufacturers accountable in state courts if they or a family member are harmed or killed by a medical device. Under a policy instituted by former FDA Chief Counsel Daniel Troy, the FDA

prohibited the public from filing lawsuits against makers of FDA-approved products.

Hinchey's FDAIA also addresses concerns about the practice of doctors prescribing FDA-approved drugs for off-label use. While there may be benefits to off-label prescriptions, there is a considerable lack of information about a drug's effects when it is used for unapproved purposes. Hinchey's bill would require doctors to inform their patients when they are prescribing a drug for an unapproved use.

Consumers Union, the independent, non-profit publisher of Consumer Reports strongly endorses the bill. Hinchey said he would begin this week to actively garner support among his colleagues in the House for the FDA Improvement Act.